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| APPLICATION NO.       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/578,507            | 05/08/2006  | Ritsuko Ehama        | 053466-0446         | 7877             |
| 22428                 | 7590        | 06/17/2010           | EXAMINER            |                  |
| FOLEY AND LARDNER LLP |             |                      | LAU, JONATHAN S     |                  |
| SUITE 500             |             |                      |                     |                  |
| 3000 K STREET NW      |             |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20007  |             |                      | 1623                |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/578,507             | EHAMA ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Jonathan S. Lau        | 1623                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 Mar 2010.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 15 and 17-21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 15 and 17-21 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

This Office Action is responsive to Applicant's Amendment and Remarks, filed 24 Mar 2010, in which claim 15 is amended to change the scope and breadth of the claim, claim 16 is canceled, claims 17 and 19 are amended to change claim dependency, and new claim 21 is added.

This application is the national stage entry of PCT/JP04/17037, filed 10 Nov 2004; and claims benefit of foreign priority document JAPAN 2003-381470, filed 11 Nov 2003; currently an English language translation of this foreign priority document has not been filed.

Claims 15 and 17-21 are pending and examined on the merits herein.

### ***Rejections Withdrawn***

Applicant's Amendment, filed 24 Mar 2010, with respect to claims 15 and 18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been fully considered and is persuasive, as amended claim 15 does not recite the genus of "a composition for increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells". Claim 18 depends from claim 15 and incorporates all limitations therein.

This rejection has been **withdrawn**.

The following are modified grounds of rejection necessitated by Applicant's Amendment, filed 24 Mar 2010, in which claim 15 is amended to change the scope and breadth of the claim, claim 16 is canceled, claims 17 and 19 are amended to change claim dependency, and new claim 21 is added. Claims 17-20 depend from claim 15 and incorporate all limitations therein.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Amended Claims 15 and 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Gan et al. (US Patent Application Publication 2004/0171693, filing date 18 Aug 2003 of parent provisional application 60/495,915, cited in PTO-892). As the filing date 18 Aug 2003 of provisional application 60/495,915 is relied upon, references to Gan et al. will be found within provisional application 60/495,915.

Gan et al. discloses a method for increasing hair growth (page 1, paragraph 1) administering a composition that comprises adenosine or AMP (adenosine monophosphate, or adenosine 5'-phosphate) (page 3, paragraph 4), meeting limitations of instant claims 16 and 17. Gan et al. discloses the composition applied to healthy hair

and scalp to maintain the normal cycle of hair replacement and discloses it will also increase the diameter of hair already present (page 6, paragraph 3). Gan et al. discloses the composition applied chronically, over the lifetime of the user, preferably for a period of at least about one month (page 7, paragraph 1), meeting limitations of instant claim 15. Gan et al. discloses the embodiment wherein the composition comprises AMP, creatine, L-carnitine and NADH (page 12, paragraph 3). Gan et al. discloses applying the composition to the hair follicle (page 2, paragraph 2) and that dermal papilla cells are present in the hair follicle (page 2, paragraph 3), necessarily meeting limitations of instant claims 18-20.

Note that the composition “increases the expression of keratinocyte growth factor (FGF-7) in hair follicle cells” is merely considered to be the mechanism of action of a treatment, a method for increasing hair growth comprising administering a composition that comprises adenosine or AMP. It has been settled that the claiming of an unknown property, such as mechanism of action, which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(e) rejection above.

That applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. Thus, the method steps in Gan et al. are the same as the method claimed herein. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims by the same active steps.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps, i.e., administering the same compound in the same amount to the same or similar patient population, are already known even though Applicant has proposed or claimed the mechanism (e.g., increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells). Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or substantially identical method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

**Response to Applicant's Remarks:**

Applicant's Remarks, filed 24 Mar 2010, have been fully considered and not found to be persuasive.

Applicant notes that claim 15 recites the applying said composition to the scalp of a subject in need thereof, where the method is for maintaining and promoting hair thickening. However, Gan et al. discloses a method for increasing hair growth (page 1, paragraph 1) and discloses the composition applied to healthy hair and scalp to maintain the normal cycle of hair replacement and discloses it will also increase the diameter of hair already present (page 6, paragraph 3). Therefore, unlike the facts in

the court of *Rapaport*, the invention of Gan et al. discloses the treatment for maintaining and promoting hair thickening, via increasing hair growth that will also increase the diameter of hair already present, which is the same purpose as the instant method.

Applicant notes that the gist of the invention of Gan et al. is the follicle-stimulating effective amount of creatine, for example at the Summary of the Invention at page 2, paragraph 2 of Gan et al. However, as recited above, Gan et al. discloses the embodiment wherein the composition comprises AMP, creatine, L-carnitine and NADH (page 12, paragraph 3). Further, Gan et al. at example 1 at page 7, for example paragraph 4, discloses that AMP was also found to increase DNA synthesis in dermal papilla cells as creatine or oxaloacetate does, implying the use of an effective amount of AMP. As Gan et al. discloses the treatment for the same purpose of the instant method, there is reason to believe that the mechanism by which the active ingredient gives the pharmacological effect would inherently be present because the treatment provides the same pharmacological effect for the same purpose of the instant method.

With regard to new claim 21 and the transitional phrase "consisting essentially of", the instant specification at page 9, lines 30-35 discloses that the instant invention may incorporate various pharmaceuticals that do not impair the desired effects of the present invention, and provides examples of amino acids, vitamins and pharmaceutical active agents at page 10, lines 10-25. The instant specification at page 10, lines 25-30 discloses that more effective hair growth effects can be expected by adding known hair growth components. MPEP 2111.03 provides 'The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those

that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976)', and "In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics." The instant specification indicates that the composition of the claimed method can contain amino acids, vitamins and pharmaceuticals that do not impair the desired effects of the present invention and that more effective hair growth effects can be expected by adding known hair growth components, therefore the phrase "consisting essentially of" of instant claim 21 is interpreted to include the prior art composition also containing creatine, L-carnitine and NADH, which provide additional enhanced hair growth effects.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Amended Claims 15 and 17-21 are provisionally rejected on the ground of nonstatutory double patenting over claims 4 and 5 of copending Application No. 11/655,134. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claim 4 of copending Application 11/655,134 recites a method comprising applying to scalp or hair roots a composition containing adenosine. Claim 5 of copending Application 11/655,134 recites a narrower genus of this method. As recited above, it is inherent that dermal papilla cells are present in the hair follicle. Therefore, claims 4 and 5 of copending Application No. 11/655,134 recite the same or substantially identical method steps as the instant claims.

Note that the composition “increases the expression of keratinocyte growth factor (FGF-7) in hair follicle cells” recited in the instant claims is merely considered to be the mechanism of action of a treatment, a method for increasing hair growth comprising

administering a composition that comprises adenosine. It has been settled that the claiming of an unknown property, such as mechanism of action, which is inherently present in the prior art method will not make the claim patentable as set forth in the provisional double patenting rejection above.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**Response to Applicant's Remarks:**

Applicant's Remarks, filed 24 Mar 2010, have been fully considered and not found to be persuasive.

As this provisional double patenting rejection is not the only remaining grounds of rejection, it is proper to maintain this rejection.

***Conclusion***

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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